

ACCE News

Vol. 8, No. 4 - July 1998

ACCE Responds to FDA ANPR

Unless the FDA heeds advice of ACCE millions of health care dollars will be flushed down the drain. See inside page 11 for the full text of ACCE's response to the FDA Advanced Notice of Proposed Rulemaking.

Painter Presents State of Clinical Engineering

See page 4 for outgoing ACCE President Frank Painter's assessment of the state of clinical engineering.

New ACCE Web Site

accenet.org

ACCE IN PHILADELPHIA

June 2 in Philadelphia the ACCE General Membership meeting and reception brought colleagues together for interesting, enjoyable and informative times. See inside page 16. Board Meeting highlights are on page 20.



Symposium Reveals Future of Clinical Engineering

Four stellar speakers and savvy moderator sparked lively exchange of views at the First ACCE Symposium in Philadelphia. See inside page 4.



*ACCE
Members
Enjoy
Annual
Meeting
and
Reception*

American College of Clinical Engineering

ACCE News

ACCE Mission

1. To establish a standard of competence and to promote excellence in Clinical Engineering Practice.
2. To promote safe and effective application of Science and Technology to patient care.
3. To define the body of knowledge on which the profession is based.
4. To represent the professional interests of Clinical Engineers.

President's Message

Frank R. Painter, frpainter@aol.com

The Annual Report

In this, my final report as your President, I summarize my Annual Report delivered at the Annual ACCE Meeting in Philadelphia, June 2.

- Successful Advanced Clinical Engineering Workshop ACEW in Washington, DC
- Sponsored an ACEW at the ASHE MTM fall meeting
- Teleconference series was well-attended and financially successful
- Over 30 new members joined ACCE last year, a 120% increase over applications received in the previous year
- Production of an outstanding newsletter delivered bimonthly to our members
- First ACCE Symposium. the first symposium ever dealing solely with clinical engineering issues.
- Budgeting improvements enabling closer monitoring of fiscal performance
- Prepared response to the FDA Advanced Notice of Proposed Rulemaking to regulate servicers and refurbishers of medical devices

I thank the officers, board members, committee members and all of you for making the above accomplishments possible and for supporting me so well in my tenure as President.

As I fade into obscurity a bright shining star rises to lead ACCE into the 21st century. Give Bob Morris the support you have given me and we will continue to successfully fulfill our mission.



ACCE News

ACCE News is the official newsletter of the American College of Clinical Engineering (ACCE).

ACCE News is a benefit of ACCE membership; nonmembers may subscribe for \$50. To subscribe call (516) 751-7244.

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Editor

Joseph F. Dyro, Ph.D., CCE
21 Bob's Lane, Setauket, NY 11733
jfdyro@aol.com; (516) 751-7244; -7802 Fax

Assistant Editors

Ted Cohen, ted.cohen@ucdmc.ucdavis.edu
Rachel Mercado, mercadr@cpmail-am.cis.columbia.edu

Photography

Sam Miller, samiller@localnet.com

Advertising Manager

Caroline Campbell, cac1@mhg.edu; (202) 877-7151 (Rates and Deadlines)

Address corrections:

Jennifer C. Ott,
3635 Vista Ave at Grand Blvd.
St. Louis, MO 63110-2520
JCottSLU@aol.com; (314) 577-8018; (314) 268-5178 Fax

ACCE

5200 Butler Pike
Plymouth Meeting, PA 19462-1298
(610) 825-6067

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ACCE on the Web New Address !!!

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Letters

ACCE News, 21 Bob's Lane, Setauket, NY 11733
516-751-7802 fax; jfdyro@aol.com

Harrington in the box

Sir-- I am a lazy writer, and most of the time a boring one, but this time after reading David Harrington's *The view from the Penalty Box* in the January 1998 issue of *ACCE News* I thought I should say something. I do not know David nor did I read the article from the *Boston Globe* or the Sounding Board column of *The New England Journal of Medicine*, but I have to say that I found the considerations reported in the article a little naive.

In a few months from now, I will enter my tenth year of consulting for both government and private (for profit and non-profit) agencies. Believe me, in all this time I have seen everything, but nothing compared to what is described in David's article. Most of the time the equipment donation problems were not the fault of the recipient. Some examples follow:

* 1988: in a small southern African country a European aid agency donated a set of devices, worth at that time one million dollars, for an intensive care unit. Nothing has been done; not one single device was ever used. In that country there was no anesthesiologist, not even a nurse specialized in anesthesia. Surgery was done by putting patients on muscle relaxants ventilating them with Ambu bags. The donated equipment was all computer-based.

* 1991: in a Central American country a non-profit agency donated hundreds of thousands of dollars in drugs. Most of them had expired shortly after arriving (there was no delay in custom clearance or distribution) and almost 20% of the drugs were supposed to be shipped in a temperature controlled box. I have to congratulate the donating drug company for the huge tax write-off they received.

* 1995: in a western African country one aid agency donated highly sophisticated medical equipment for only three specialties in the teaching hospital. Besides the fact that most of the equipment was never used before in that country, this one donation doubled the country's estimated total equipment replacement value.

Donation guidelines are great and the World Health Organization (WHO) does what it can to apply the guidelines. The person I know at WHO-Geneva who is working on this issue is very clear on whose guidelines are used (ACCE guidelines are not the only available guidelines in the world). However, it is my opinion that the point is not which guidelines to use, the point is not what David says "*It appears we have a problem in getting information on what we have done out to the appropriate organizations, both nationally and internationally*", and the point is not who is to blame in a particular agency or government. The point is that there are too many interests all over the world, from political to commercial, from private to public, from for-profit agencies to the charitable action of a small church in a little town that decides that some African mother is suffering and to make that mother feel better donates to the local hospital a mammography unit (West Africa, 1993/4, never worked, no manuals). The sequence is too big and the problems too many to be able to face them all. If researched, I would bet that one would not find any minister of health in a developing country or aid agency coordinator who did not know of the existence of donation standards and guidelines. Almost everyone I spoke with knows that there are standards for equipment for a certain level of care and essential drugs

lists. However, when large medical equipment companies, traders, or drugs manufacturers are bidding for a huge amount of money anything happens and all our work just disappears in seconds. Saying this, I do not want to state that there is no hope, but from the reality to the considerations written in the article there is a huge gap, and a real Copernican Revolution is needed.

In April, at the African Federation for Technology in Health Care (AFTH) meeting in Harare, Zimbabwe, I was expecting to see some of my colleagues from the ACCE or from other powerful international organizations who are working on international cooperation. Unfortunately, only one European aid agency was represented. There were consultants of WHO-Afro, including the Deputy Director, and of WHO-Geneva. There were technicians and engineers from almost all the sub-Saharan countries and few free-lance consultants who were working nearby. Presumably they could invest some of their own money to fly to Harare. A lot was said about the various problems the Ministries of Health of developing countries face related to their dependency on foreign donations and financing. I personally saw great work done in the local Ministries of Health and much more professionalism than ten years ago when I started. But, is all this sufficient to contrast the power of some multilateral financing agencies or the money-hungry drug and medical equipment corporations? Fault and truth do not stay on one side or the other, but some radical action should be made. Otherwise, all our considerations are just a writing exercise and nothing more.

Enrico Nunziata
Clinical Engineering Consultant
engbio@sortmoz.com

Miller in the box

Sir-- As a proud (and relatively new) member of ACCE and a long time member of AAMI, I thought that these two organizations were highly symbiotic, that there were strong reasons for them both to exist, and that certainly they were no threat to each other. Moreover, I thought that any possible conflicts had been resolved over the past years of mutual existence. I was disappointed to discover that these thoughts were naïve and that, in particular, AAMI refuses to carry paid advertisements from ACCE such as for the recent, and highly successful, **First ACCE Symposium**. This kind of pettiness has no place in a supposedly professional organization whose stated objective is to serve its membership, as opposed to simply serve itself.

As a member of AAMI, I have written to Mike Miller, AAMI's President and CEO, to protest AAMI's refusal to carry ACCE advertising. I suggest that other ACCE members, who are also paying substantial dues to AAMI, do the same. Mr. Miller can be reached at: AAMI, 3300 Washington Blvd, Suite 400, Arlington VA 22201-4598; or call him at 1-800-332-2264.

William A. Hyman
Texas A&M University
whyman@tamu.edu

ACCE News

The State of Clinical Engineering

Frank Painter, fpainter@novamedcorp.com

I see change all around me but I find the environment to be good. Opportunities for clinical engineers are increasing for three reasons:

1. The use of technology is increasing. Number of beds will eventually decrease to 50% of 1980 levels.
2. Pressures on hospitals to be creative in service management continue to increase.
3. Asset management and outsourcing are concepts that have become firmly routed in the administrator's psyche.

The resultant effect of the above will be an increase in the need for clinical engineers, technology consultants, and technology managers.

In short, our future possibilities are unlimited. Believe me when I say it is rosy out there if you step forward and make the commitment.

As a president perhaps I can get away with the following admonition and charge: *Don't ask what this profession can do for you, ask what you can do for the profession.*

My action plan for you all is to learn, write, teach, participate and take risks to do what you think is right. While you are doing all this, look in the mirror on the wall every once in a while. Ask *What value do I bring to the organization? What do my employees, co-workers, boss and colleagues see in me that has value?*

Painter's four Point Success Plan

1. Help others understand things
2. Be conscious of your cost
3. Speak the language best understood by those to whom you are speaking
4. Make yourself understand problems

Keep doing more of the above! If we do these things the future in this profession will be rosy.



First ACCE Symposium

The Future of Clinical Engineering

Joseph F. Dyro, Ph.D., CCE, FACCE

May 30, 1998, a historic day in the calendar of the American College of Clinical Engineering, saw clinical engineers gather in Philadelphia for the **First ACCE Symposium, The Future of Clinical Engineering**. ACCE President Frank Painter noted that the College had matured to the point of having its own program, unique in its focus on clinical engineering professional matters. ACCE regards the Symposium as an important part of its educational program along with Advanced Clinical Engineering Workshops, Audio-Teleconference Series, web page, special publications and the newsletter. Ira Tackel moderated the event held at Thomas Jefferson University where he directs the Biomedical Instrumentation Department. Extraordinarily, knowledgeable panelists Malcolm Ridgway, Larry Hertzler, Tom Bauld, and Greg Davis, cumulatively representing 100 years of clinical engineering experience, gave informative talks, sparking lively discussion, ideas and useful information interchange in an Open Forum which followed. Jennifer Ott, ACCE Secretary, excelled as Symposium Committee Chairman.

Moderator Tackel, focused the Symposium participants on the future saying, *"If we hide behind the past we will never get to the future."* Thomas J. Bauld, III, Ph.D., Manager of Biomedical Engineering, University of Michigan Health System and ACCE Founder and Past-President, stressed that acquisition and planning strategies must look at overall return on investment. Post-implementation studies of programs claiming financial and clinical rationale are rarely performed to determine if initial

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goals were achieved. Saying, “**never say no**,” Bauld advised that educating ourselves and our staff, developing new skills, maintaining flexibility and adaptability, and seizing opportunities of value to the institution are key to in-house department growth and success. Greg Davis, CCE, Director of Engineering Services, National MD, addressed value in cost control, synergy in the consolidation of organizations, and government intervention in service. Offering that **clinical engineers need to engineer the clinical environment**, he pointed to opportunities in areas such as OR safety, ICU equipment layout, and device applications education. Larry Hertzler, PE, CCE, Vice-President and Chief Operating Officer, Medical Technology Management, predicted **synergy-ships**, i.e., consolidations and mergers that benefit both partners, increasing the value of the whole. Clinical engineers must get tied into clinical outcomes which together with cost, customer satisfaction, and code compliance are the real performance measures. According to Malcolm Ridgway, Ph.D., Vice-President of Technology Management Master Plan, COHR, the **New Frontier for clinical engineering lies in knowledge-based services**: managing the equipment budgeting process and re-engineering technology intensive services (TICS) such as diagnostic imaging, lasers, and cardiovascular services. While the bread and butter services of maintenance management and regulatory compliance will remain, clinical technology optimization (CTO) services will increase. For every dollar saved in the traditional areas, two dollars can be saved in CTO. More services will be provided on site; whether the support is on the payroll of the hospital or the contractor is immaterial. A score of job descriptions emerged as Ridgway challenged the attendees to state what they do as succinctly as he has, *I help hospitals solve their equipment problems*.

The Open Forum put out-sourcing vs. in-sourcing in clear perspective. As Alan Lipschultz said, it is not an either-or situation, both strategies are tools for the effective technology manager. Martina O’Brien suggested ways of demonstrating best value in clinical engineering. Ira Soller stressed the importance of telling your institution what a good job you are doing. Attendees agreed almost unanimously to the uselessness of electrical safety inspections. Most agreed also that the FDA is tilting at windmills as it attempts to regulate service providers; the accident data simply doesn’t justify regulatory action. During the Forum, Tom Bauld and John Hughes remarked that HealthTech ‘98 drew the best balance of professions ever seen to discuss issues dealing with equipment management and featured the leading edge technologies in imaging, telecommunications and radiology.

An afternoon poster session featured the following presentations: *Surgical Fires Can Be Prevented* by Mark Bruley, *Some Perspectives on Clinical Engineering Consulting* by Sam Miller, *College of American Pathologists Device Inspection Rule Changes* by Dave Francoeur, *FDA’s Advanced Notice of Proposed Rulemaking* by Tom Bauld and *Year 2000* by Martina O’Brien.

Clinical engineers, gaining more confidence in their paths to the future from that historic day in Philadelphia, are setting their sights on Symposium 1999. Proceedings and video tapes of the First ACCE Symposium are available for purchase. See page 13 for more on the First ACCE Symposium.

Order the 60-page
ACCE Symposium Proceedings
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Meetings

AAMI EMC Committee Meeting EMBS

Robert J. Berkovits

Clinical Engineering, Touro College School of Health Sciences

On 4 June 1998 the AAMI EMC Committee met in Philadelphia. The meeting was chaired by Nick Tongson, Director of Standards for AAMI. Two items on the agenda were the review and comment on the International Standard IEC 60601-1-2, "Medical Electrical Equipment" Part 1: General requirements for safety 2. Collateral Standard: EMC - Requirements and tests; and a discussion of problems and approaches to resolving the interference between digital TV (DTV) transmissions and medical telemetry systems. The DTV discussion was led by Thomas P. Stanley, Ph.D, Chief Engineer Wireless Telecommunications Bureau of the FCC. The main emphasis was on the existing problems with medical telemetry in the 450 - 470 MHz band. TV stations should make every effort to identify health care facilities in their broadcast coverage area and notify them in advance of their initial on the air test dates. FDA representatives were Jeff Silberberg and Don Witters. ACCE member Dr. Joseph P. McClain, Walter Reed Army Medical Center representative, will be the AHA liaison. Other attendees included representatives from Hewlett Packard and ECRI.

Information on the DTV interference problem can be viewed at web sites www.fda.gov/cdrh/safety.html and at www.fcc.gov by selecting the appropriate menu items.

New York Metropolitan Area Clinical Engineering Directors

Ira Soller

The New York City Metropolitan Area Clinical Engineering Directors Group met on May 26 and July 14, 1998. Lectures at these meetings were *Medical Lasers: Where we are and where we are going?* presented by Valentin Grimblatov, Biomedical Laser Specialist of Columbia Presbyterian and *Troubleshooting and care of flexible endoscopes* presented by Scott Reifsnnyder, Director of Operations of MedServ International. Following the lectures, member discussion centered on the Y2K problem and the tendency for some manufacturers to declare equipment obsolete rather than provide compliance information, FDA initiatives relating to regulation of device servicing, recommended providers of equipment calibration services, pitfalls of selling used hospital equipment and recent hospital acquisitions and mergers. The meetings were hosted by ACCE member Mike Mirsky of St. Luke's Roosevelt. For meeting information or manufacturers/ vendors interested in making future presentations, contact Group Coordinator Ira Soller, Director of Biomedical Engineering, State University of New York, Health Science Center at Brooklyn, 450 Clarkson Ave, SMIC Box 26, Brooklyn, NY 11203, (718) 270-3192; (718) 270-3194 Fax

The Seventh Annual National Expert Witness and Litigation Seminar

Joseph F. Dyro

June 18-19, 1998 at Hyannis, Massachusetts expert witnesses and litigators gathered to learn at this annual seminar. Keynote addresses were presented by the Honorable Robert W. Pratt, *A view from the bench: Expert witness testimony*, and Jan Richard Schlichtmann, Esq., *Use and abuse of expert witness testimony in high stakes litigation*. ACCE member Joseph F. Dyro made two invited presentations: *Methods for analyzing home care medical device accidents* and *So, you want to be in pictures? Beware! What you shoot can be used against you!*

The seminar sponsored by SEAK, Inc., Legal and Medical Publishers, of Falmouth, MA is an excellent opportunity for clinical engineers to learn how to improve the skills needed to deal effectively in litigation matters. Clinical engineers are particularly helpful to the court in product liability cases involving medical devices because of their hands-on familiarity with safety and design aspects as well as acquisition, inspection, application, and service issues.



Seminar organizers Babitsky, Mangraviti, and Colombaro with ACCE's Dyro

ACCE News

People on the Move and in the News

Welcome to ACCE!

The ACCE Board unanimously approved the following recommendations of the Membership Committee:

Individual Member

Marcia Arney

Associate Member

Manny Roman

Student Member

Robert J. Berkovits

*Congratulations,
new members!*

Bauld to Premier

Dr. Tom Bauld, is joining the Clinical Technology Services Division of Premier Inc., a large, nationwide hospital purchasing group. Initially, he will be serving as the corporate level coordinator for the biomedical equipment Year 2000 process for the thirteen hospitals of the Mercy Hospital System in Michigan and Iowa.

Miller on the Move

Sam Miller joins *ACCE News* as Staff Photographer.

The *Journal of Clinical Engineering* has chosen Miller to head a new department, the Consultant's Column.



Miller has also agreed to chair the ACCE International Committee replacing Al Levenson.

Ott a Mother

ACCE Secretary **Jennifer Ott** gave birth to a son, Spencer James. Proud parents, Jennifer and Jim report that Spencer entered the world at 12:36 PM CST on June 25, 1998 weighing in at 8 pounds 9 ounces and measuring 22 inches long.

Jennifer says mother, father, and Spencer are doing very well. Days and nights are a bit mixed up (she thinks the new arrival is just a party animal!), but naps are a wonderful thing!

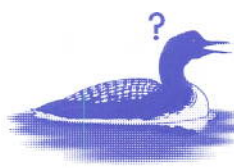
Evans at HTMS

Gary Evans recently joined HTMS as Vice President of Clinical Engineering. The Laurel, MD firm provides a complete range of consulting and technology management services but specializes in working with in-house technology departments to reduce service contract costs, provide training, and prevent outsourcing.



Dyro Calling Loons

Dr. Joseph F. Dyro competed in the Second Annual Belgrade Lakes, Maine Loon Calling Contest held July 12. His sister, Dr. Frances M. Dyro also competed.



ACCE Board Nominees

Nominees announced at the June 2, 1998 ACCE Annual Meeting are **Bob Morris**, President, **Bryanne Patail**, Treasurer, **Jennifer Ott**, Secretary, **Joseph McClain**, member-at-large and **Caroline Campbell**, member-at-large.

Advocacy Awards to Shepherd and Shaffer

Tom O'Dea Chairman of the Advocacy Committee announced the winners of this year's awards at the Annual Meeting in Philadelphia. **Marvin Shepherd** won the Professional Achievement Award and **Mike Shaffer** won the Professional Development Award.

Journal of Clinical Engineering Managing Editor Tim Baker presented winners with a one-year subscription to the *Journal*.



Baker, O'Dea and Shepherd

Wang to Brazil

Dr. Binseng Wang will conduct a three-day workshop on **Strategic Planning and Technology Assessment**, August 14-16, 1998 in Saõ Paulo, Brazil.

The View from the Penalty Box

David Harrington, davesbt@kersur.net

As I walked around the show floor in Philadelphia I was struck by the number of booths for companies doing repairs on fiber optic scopes and those selling management systems for equipment. It became clear to me that we still have a long way to go in managing the technology within our hospitals. These observations are based on the following.

Fiber optic scopes have been around for many years but the same problems still seem to be present in them now as when they first came into use. How many of these problems have been caused by design flaws, use, or reprocessing techniques is just starting to be talked about in the literature. ACCE member Tom O'Dea has done us all a favor in publishing his findings on scopes. We all should try to apply his findings to our own institutions and cut down on the number of scope problems.

While I did have time to go through all of the management systems, those that I did were more for financial reasons than for reliability of devices. Several of the systems could not do repair history comparisons of devices easily. But they could provide cost comparisons on similar devices. To me the problem histories are very important when planning for replacements of existing technology or adding additional devices. Several also had no field where the software level of the device could be displayed. This can be a critical piece of information when doing failure analysis on devices. Unfortunately many management systems focus on finances not reliability. I have always contended that if you have good devices reliability your finances will be fine. Maybe I missed something in my thinking?

A problem, at least for me, was that activities were taking place in three buildings. That made it more difficult to find people with whom you wished to talk. There was no central point by which everyone had to pass each day where you had a good chance of finding the person(s) your wanted to see.

In listening to some of the papers and hallway conversations many of our colleagues have a very poor background in the history of our profession. I sat through



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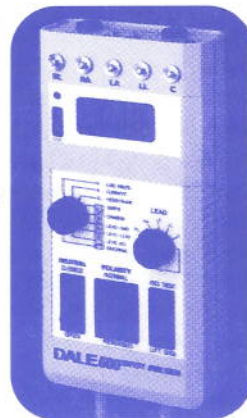


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several papers rehashing information presented years ago. Unfortunately this information was never published, other than in meeting abstracts, making it difficult for our colleagues to find and to apply. As a profession we need to publish more of our work so others will not have to reinvent what we have already developed. Many of those who have never published or publish once every 10 years are the very people complaining about the lack of information in journals that serve our profession.

Now comes the most difficult part for me. I must announce that I was wrong on the slowest arm in the world. For years I thought it was our new President Bob Morris. This meeting proved me wrong. The new champ, at least in the eyes of many is Joe Dyro, our editor. So Bob I am sorry for all the jokes on your slow arm I apologize.

Bob and I will be spending time together in Calcutta doing an install in July and I just hope that Bob does not try to regain the title of the slowest arm. Have a great summer and please publish so we all can learn from what you have accomplished.



CLINICAL ENGINEERING PROFILES

Adriana Velázquez de Peynetti

In high school I knew I wanted to work with people from around the world. A psychologist advised either computer engineering or international affairs; so I enrolled in a Mexican university to study cybernetic engineering. At a friend's suggestion I enrolled in chemical engineering at a more prestigious university. In 1978 my courses began but soon I discovered biomedical engineering. A difficult first semester allowed thoughts of a career as a French teacher to fill my head. Sharing my concerns between semesters with my parents together with my Aunt Lolis, colleagues and friends I found strength to continue. Encouraged and excited with biomedical engineering I excelled in the second semester and knew it was the right path. I discussed biomedical engineering with the first biomed in México who had graduated recently.

Mexico's Universidad Iberoamericana began its Biomedical Engineering program in 1974. When I enrolled there were just four classes in México ahead of me each with about 8 to 12 engineers. At the Universidad Autónoma Metropolitana, which started its program six months later than Iberoamericana, about 20 engineers were ahead. I attended and helped organize the national conferences of Mexican Society of Biomedical Engineering. Half the biomedical engineering student body were women. As a final project three of us developed a vibrotactile aid for profoundly deaf children. After receiving the BS in 1983, I taught at the University and worked for ISSSTE, a government institution. There our team of three industrial designers, a nurse and an architect designed ambulances, nebulizers, and small devices for ISSSTE hospitals.

I entered the Masters Program at Case Western Reserve University in January of 1985. Arriving in winter was not the best, but the warm spirits in CWRU Biomedical Engineering with friendly graduate students, inspiring professors like Dr. Janie Fouke and Dean Topham, and multilingual, multicultural friends in Steiners International Student House carried me through graduation. It was a wonderful year of gaining extensive clinical engineering experience at Metropolitan General Hospital in Cleveland. The clinical engineers encouraged me to face clinical problems and to solve them technically and managerially. Even before Cleveland, I desired to work in clinical engineering at a Humana Hospital in Mexico City that opened in 1984. Imaging my surprise when the man in charge of maintenance said I couldn't apply since I was a woman! Undaunted I talked to the administrator who one year later called Cleveland with a job offer. I recommended two former biomedical engineering teachers in Mexico to the Administrator and agreed to join Humana upon my return.

Upon my arrival, Humana Hospital was bought by a Mexican entrepreneur. The head clinical engineer had to leave and recommended that I take charge. I started with a 6-meters-square biomed shop, one technician and a student for a 150-bed institution with 6 ORs. The owner and President of the Hospital entrusted the technology in the hospital to me. Finding corruption in the maintenance personnel and with the support of the President, I was placed in charge of Plant Engineering, Maintenance and Biomedical Engineering. Soon, I divided the areas assigning greater space for each one. With complete support from the medical, financial and management directors I assigned new divisional tasks and hired more personnel. Lasers, imaging equipment and clinical lab automated equipment were on contracts, with the rest handled by Biomedical Engineering. Our department of 10 also did teaching and training. In the meantime, I married Hector, who was always supportive but sometimes jealous. The demands of the hospital often found me working 10- to 12-hour days, weekends and holidays.

Now the tree is blooming. The seeds were planted and nourished. Students and workers were trained and now are clinical engineering department heads in most of the important hospitals in Mexico and in some companies. At Angeles Hospital, aware of the importance of technology in increasing health care quality, a Technology Management division was formed which directs all plant engineering, communications, biomedical engineering, maintenance, laundry, and several small departments. A biomedical engineer serves as corporate technology officer. In January 1991 I was invited to participate in the ACCE Advanced Clinical Engineering workshop held at the Pan American Health Organization offices in Washington, DC. As I sat with colleagues from around the world I saw my dream come true. I could do something not just for Mexico but for other countries, as well.

My life changed radically when Hector and I learned we were expecting twins! I quit the hospital to become the full time mother of Bruno and Paola. Deciding they were my most important project in life, with the support of Hector and my parents, I

left hospital work. I continued to attend conferences and meetings and began to write. I joined and held various offices in the Mexican Hospital Association and Mexican Biomedical Engineering Society. I went from student to instructor teaching in the next ACEW in Boston. More travel took me to Rio de Janeiro to the IFMBE Conference and CORAL reunion, where I was elected vice-president, to Cuba and Guatemala for PAHO, and to several Mexican conferences. In Nice 1997 I began my tenure on the board of the Clinical Engineering Division (CED) of the IFMBE. I am organizing the 1st Conference in Biomedical Engineering, the Coral meeting and an ACEW for November of this year in Mexico.

My overriding mission is to convince everyone that clinical engineers are needed to decrease costs, to control technology, and to enhance patient care. While the children are at school in the morning I consult in private and public hospitals. Summers are reserved for family. I have had good results creating and restructuring clinical engineer departments.

I am grateful to so many. To my mother, a thanatologist and volunteer with terminally ill cancer patients, for showing me what love is and teaching me that love can do everything, for giving me constant support, and for convincing me to live life to the fullest as if each day is the last day of my life. To my husband, Hector, for his unflinching support and encouragement of my professional goals, for being such a great father, and for his love. To my twins, Bruno and Paola, now almost six, for teaching me patience, love, humility, fantasy and dreaming, willingness, and most importantly happiness learning to enjoy life, water, animals and friends. To all my colleagues and friends for directing our profession to help those in need. And to my recently deceased father, may he rest in peace, for teaching me to do things cleanly, honestly, and responsibly forever holding high the name of Mexico. I will always keep this in mind, and I will keep on striving in his memory.



Paola, Bruno, and Adriana selecting pastries

photo by Joe Dyro

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ACCE products

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ACCE Responds to FDA

Should medical device servicing, remarketing and refurbishing organizations be regulated by the FDA? In December 1997, the FDA officially published its "Advanced Notice of Proposed Rulemaking" (ANPR). The purpose of the ANPR was to promote official public comment on the FDA's proposal to develop regulations, similar to its Good Manufacturing Practice (GMP) rules for manufacturers, and apply them to medical device servicing, remarketing and refurbishing organizations. The FDA was seeking public comment, by June 29, 1998, from the user community (e.g. hospitals, long-term care facilities, ambulatory surgery centers etc) as well as the organizations that are proposed for further regulation (i.e. ISOs, in-house service departments, re-marketers and refurbishers). As the major Clinical Engineering advocacy organization, the ACCE response to the FDA spells out several concerns that many clinical engineers have with this proposal for further governmental regulation. In light of its importance, the editors of the ACCE News have chosen to print the ACCE response in its entirety. The following is that response:

June 23, 1998

Dockets Management Branch (HFA-305)
Food & Drug Administration, Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

Re: Docket Number 97N-0477

Dear Sirs,

The American College of Clinical Engineering (ACCE) appreciates the opportunity to comment on the Advanced Notice of Proposed Rulemaking titled **Medical Devices: Refurbishers, Rebuilders, Reconditioners, Servicers, and "As Is" Remarketers of Medical Devices; Review and Revision of Compliance Policy Guides and Regulatory Requirements; Request for Comments and Information.**

The ACCE consists of over 150 of the most highly experienced clinical and biomedical engineers in the United States and around the world. These individuals have established and managed many of the largest hospital based clinical engineering / biomedical engineering departments in leading community hospitals and academic health care systems. Many of our members also have experience in the third-party independent service market. They are active in device service management, development and application of maintenance management systems, device safety and performance standards, as well as the education of engineers, technicians, and clinicians in the biomedical community. Their duties include management of the 1990 Safe Medical Device Act processes, device recall management, investigation of device related incidents, service on Safety Committees, and management of the biomedical equipment technicians. The ACCE is thus eminently qualified to provide the FDA a well balanced opinion that is based on extensive experience.

Our organization and its members have, as one of their major priorities, the promotion and safe application of medical devices in healthcare. We support efforts that demonstrate a positive and cost-effective contribution toward that goal.

In addition to answering the specific questions to which a response was requested by the FDA, we would like to provide comments on several other issues raised in the ANPR.

In general, the ANPR document addresses two entities, remarketers that are involved in the commercial distribution or re-distribution of used medical devices, and servicers who are engaged by owners of medical devices in performing corrective and periodic maintenance of medical devices. There should be a clear distinction in the way the FDA deals with these two disparate entities.

1. **Has the FDA appropriately defined the terms "refurbisher," "as-is remarketers," and "servicers?" If not, what changes to those definitions should be made?**

The definitions provided by the FDA should be revised. Only two definitions are needed to cover the activities in medical device servicing and remarketing.

ACCE News

ANPR Term & Definition	Suggested Term & Definition
Refurbishers: Persons, who for the purpose of resale or redistribution, visually inspect, functionally test, and service devices, as may be required, to demonstrate that the device is in good repair, and performing all the functions for which it is designed. The device may or may not be cosmetically enhanced. Preventive maintenance procedures may or may not be performed.	Remarketers: Persons who resell or redistribute devices. Unless qualified by the term “as is,” the devices sold must be performing according to the original manufacturer’s safety and performance specifications.

ANPR Term & Definition	Suggested Term & Definition
Servicers: Persons who repair a device or return it to the manufacturer’s fitness for use specifications, and perform the manufacturer’s recommended scheduled preventive maintenance. Servicers do not significantly change a finished device’s performance or safety specifications, or intended use.	Servicers: Persons who perform inspections, corrective and preventive maintenance, without changing a finished device’s performance or safety specifications, or intended use.

The reason we believe that there is no need to have two distinct classes, one for refurbishers and another for “as is” remarketers, is because the same person/organization can be involved in both sets of activities. The distinction often can only be made on a product by product basis.

On the other hand, we would like to point out that the remarketers and servicers are two widely different types of entities. The first ones are involved in the commercial distribution or re-distribution of used medical devices, while the second provides corrective and periodic inspection and maintenance services to medical devices. While, a single organization can be both a remarketer and a servicer, typically one activity exceeds the other by a wide margin. In contrast to the rebuilders/reconditioners, both share the common denominator of not significantly alter a finished device’s performance or safety specifications, or intended use.

It may be argued that remarketers and servicers are different in many aspects, such as ownership, relationship to patients, economic incentive, core activity, corporate goal, and liability risk. To the best knowledge of our members, there is no data to substantiate that the work performed by in-house departments is consistently superior (or inferior) to that provided by independent service organizations (ISOs) or by the original equipment manufacturers.

The servicer universe is even more diverse than the remarketers. Besides the in-house clinical engineering departments staffed by the organization’s employees, there are in-house departments staffed by a outside non-profit or for-profit organizations, service organizations owned and operated by manufacturers, service organizations that are jointly sponsored by a number of healthcare organizations (known as “shared services”), for-profit service organizations that belong to non-profit healthcare organizations, service companies that are independent of manufacturers and healthcare organizations (the truly “independent service organizations - ISOs”), and combinations thereof.

In our collective opinion, the major difference between remarketers and services is in the products they provide. Remarketers sell equipment while servicers sell service.

2. What evidence exists regarding actual problems with the safety and/or performance of remarketed devices that are the result of remarketing? Specific examples should be submitted.

Our members have reviewed their databases of medical device service as well as their incident report files and can find barely a half dozen instances where inadequate servicing could be attributed to a subsequent patient injury, including those incidents in which injury was prevented by clinical intervention. The review encompasses literally hundreds of thousands of devices, millions of work orders, and hundreds of incident files.

Over the past 10 years, one of our members worked as a consultant and has investigated hundreds of incidents. He reported that he can only recall seven servicer-related adverse events.

Also, there is no clear distinction in terms of service quality between equipment that was serviced by in-house staff, third-party-paid in-house staff, shared services, ISOs, service depots, and manufacturer representatives. There are, however, many articles written in the decades of 70 and 80 reported incidents and accidents caused by medical equipment that failed due to the lack of service.

During the final phase of discussion of the CGMP in the fall of 1995, the FDA was not able to provide data to substantiate the need for regulating repairs and maintenance services. At that time, the FDA alleged that the MDR database did not contain sufficient information regarding service history. However, ECRI staff performed an extensive text search on the same database and concluded that the number of problems that were attributed to service was negligible. Since then, the FDA has collected a huge database of device problems through the 1990 SMDA reporting process (known as the MedWatch program). It would seem logical that the FDA would present a conclusive analysis of the collected data of patient injuries or deaths prior to proposing additional costly regulations. Without objective data, it is difficult for us to accept and support regulations that do not seem to be needed to protect public safety.

We would also like to point out that there are comments in the ANPR that appear to use commercial competitiveness arguments as a basis to extend the GMP regulations. The FDA should only consider threats to public safety as arguments for regulation. Commercial competitiveness arguments are inappropriate justification for the FDA to initiate regulatory activities.

3. What is the appropriate level of regulatory controls that should be applied to persons who remarket devices? and

3.1 Remarketers

To reemphasize, the group consisting of refurbishers and remarketers are involved in remarketing medical devices they acquire and resell. Title to the devices passes from a healthcare institution user, to them and then to another healthcare user. Their activities are in some ways similar to remanufacturers whose activities "significantly change the finished device's performance or safety specifications or intended use" as defined in the Quality System regulation. However, these remarketers don't change the device's specifications, rather they may perform a variety of maintenance tasks to correct deficiencies, verify proper operation, and perhaps extend the longevity of the device through preventive maintenance.

The ACCE recommends requiring registration of these companies or persons in order to allow for tracking the location and ownership of medical devices. They should register and notify the original equipment manufacturer (if known) of the new owners name and location. This would permit the distribution of recall and service bulletin information to the owners of equipment regardless of the number of sales transactions. Identification of the remarketer and the condition of the equipment should be part of the transaction documentation.

3.2 Servicers

It seems that the FDA may not be fully aware of the current methodology of device service support or the resources that would be necessary if new regulations were enacted by the FDA.

The vast majority of American hospitals are already evaluated on their processes and procedures for safe and effective equipment management programs by the Joint Commission for the Accreditation of Healthcare Organizations (JCAHO). These hospitals, as well as many outpatient facilities, and home health organizations must have an Equipment Management Plan that complies with the JCAHO Environment of Care standard. The standard requires quality processes, continuous performance improvement, and measured performance indicators. JCAHO also requires evidence of competency of all employees, servicers and users. Compliance with these voluntary standards is a highly effective motivational tool for healthcare institutions since it is publicly available and used by insurers, Medicare, Medicaid, and other Health Care Financing Administration (HCFA) programs for reimbursement. The economic consequences of failure to achieve compliance can be disastrous. The majority of independent service organizations (ISOs) that provide service to JCAHO accredited healthcare institutions are already required by these institutions to comply with the JCAHO standard.

Most clinical engineers and biomedical equipment managers that work for hospitals and service organizations and are members of professional and trade organizations such as ACCE, ASHE, and AAMI. These organizations educate their members and promote effective equipment management. Systems for maintenance activities including detailed inspection procedures are in place in most institutions. Organizations such as ECRI provide subscription services that include detailed performance test procedures for medical devices. ASHE has had similar compendiums of medical device test procedures for over twenty years.

Any proposed regulations will add to the already significant administrative burden imposed on hospitals by the FDA for User Problem Reporting and Device Tracking. These SMDA-mandated activities have not yet been demonstrated to be either effective or beneficial to the healthcare of our patients. In fact, the recent FDA Modernization Act is requiring the FDA to limit the mandatory MedWatch program to a small number of hospitals. The administrative activity that will be required to comply with the contemplated regulations would add

ACCE News

considerable expense to the costs of patient care when the healthcare industry is under dramatic pressures everywhere to reduce costs and improve the quality of service. A gross estimate of the additional cost is provided by the following example.

It is fairly well established that the cost of maintenance is approximately 8 % of the value of the capital equipment in the facility. For a hospital with a \$50,000,000 inventory, that means \$4,000,000 in maintenance expenses. If the cost of the regulation adds only 2% to the cost of maintenance, that would amount to \$80,000 annually for this example institution. There is no evidence that this cost could be justified in terms of the public health.

Furthermore, the time wasted by service staff complying with these requirements will, in fact, be counter-productive to good device service management, since less time will be available to attend to needed corrective service activities, scheduled device inspections, and operator training. Managers of hospital service organizations are continuously evaluating the services they provide to ensure the services are adequate, sufficient, meet their customers needs and regulatory requirements, and add value.

Considering that there is no substantial evidence that a significant problem exists with activities performed by in-house or third-party service providers, any significant expense cannot be justified in any cost-benefit analysis. Instead, the ACCE recommends that the widely respected and universally accepted voluntary accreditation standards from organizations such as JCAHO, the American Osteopathic Association (AOA), or the ISO 9000 process can be utilized for servicers of medical devices.

4. Should refurbishers, “as is” remarketers, and servicers be subject to the same or different regulatory requirements?

As mentioned in our response to question #1, we do not believe it is wise to subject the remarketers and servicers to the same regulatory requirements. Even if the FDA could prove that there is a need to regulate remarketers and servicers, it will be difficult for the FDA to write a single set of regulations that will cover remarketers and servicers.

If regulations are issued for remarketers, there is a need to identify the products that are sold in “as is” condition versus those without such qualification. Whenever an “as is” device is sold, both the seller and the buyer should be required to sign a document acknowledging that the device that is being transferred may not be in condition to perform according to the original manufacturer’s safety and performance specifications. If the buyer is going to resell the “as is” device, he/she is required to either alert the next buyer that the device is again sold in “as is” condition, or restore it to perform according to the original manufacturer’s safety and performance specifications.

5. FDA is specifically considering whether to propose rulemaking regarding modified registration, listing, and CGMP requirements of these types of remarketers, or whether to make some or all of these three controls voluntary.

ACCE does not believe mandatory regulation is needed for servicers, but do agree that voluntary quality standards can help improve the services provided by servicers. We firmly believe that quality improvement is a continuous process that is beneficial for all involved, i.e., the providers, the customers, and most importantly, the patients.

In summary, we feel that the FDA has not demonstrated a need to include servicers in a regulatory environment similar to medical device manufacturers, rebuilders/reconditioners, or remarketers. There is no evidence to show an improvement in patient safety will occur and the economic burden that would be imposed on healthcare service providers is not in any way commensurate with any limited benefits that may accrue.

We propose that the existing voluntary JCAHO accreditation process be considered sufficient and adequate for servicers “As Is” Remarketers need little regulatory management. Remarketers, should be regulated in a manner less comprehensively than the original equipment manufacturers.

The JCAHO, ECRI, professional organizations such as the ACCE and ASHE, and trade organizations such as AAMI, HIMA, and MDMA should be invited to contribute to the continuous improvement of these voluntary standards.

We hope that our comments are seriously considered as the decisions are made. We welcome the opportunity to meet and discuss further with your staff any issues relating to medical device management and safety

Sincerely yours,
Frank R. Painter, CCE
President

FIRST ACCE Symposium



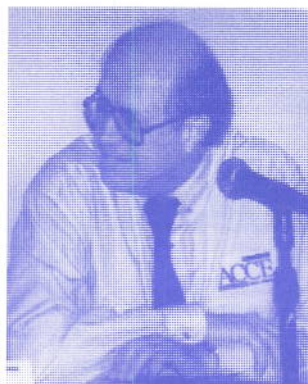
If we hide behind the past, we will never get to the future says Moderator Ira Tackel



The new frontier for clinical engineering lies in knowledge-based services: managing the equipment budgeting process and re-engineering technology intensive services.



Larry Hertzler predicts synergy-ships



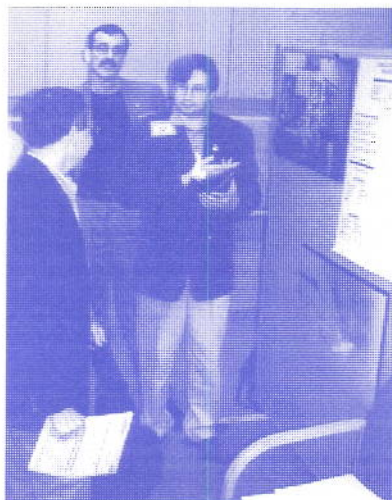
Bauld's philosophy: Never say no.



Clinical engineers need to engineer the clinical environment, Greg Davis



What do I do? I help hospitals solve their equipment problems, says Malcolm Ridgway



In his poster, Mark Bruley explains fires in the OR



Multi-talented President Painter hawks shirts

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ACCE Annual Meeting 1998



Morris, Bauld and Hernandez Plan

while



Jakniunas, O'Donnell, Hall and Patail Ponder



Out with the old, in with the new:
Outgoing President Painter (r) congratulates
incoming Morris



Patail and O'Dea toast to the future of ACCE



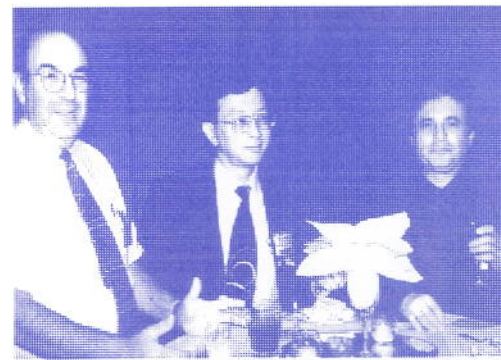
Betts, Campbell and Johnston enjoy the moment



All smiles at the gala ACCE reception



Best meeting yet



Bell (l) clears throat to sign aria. Wang (c) and Shnyder wonder

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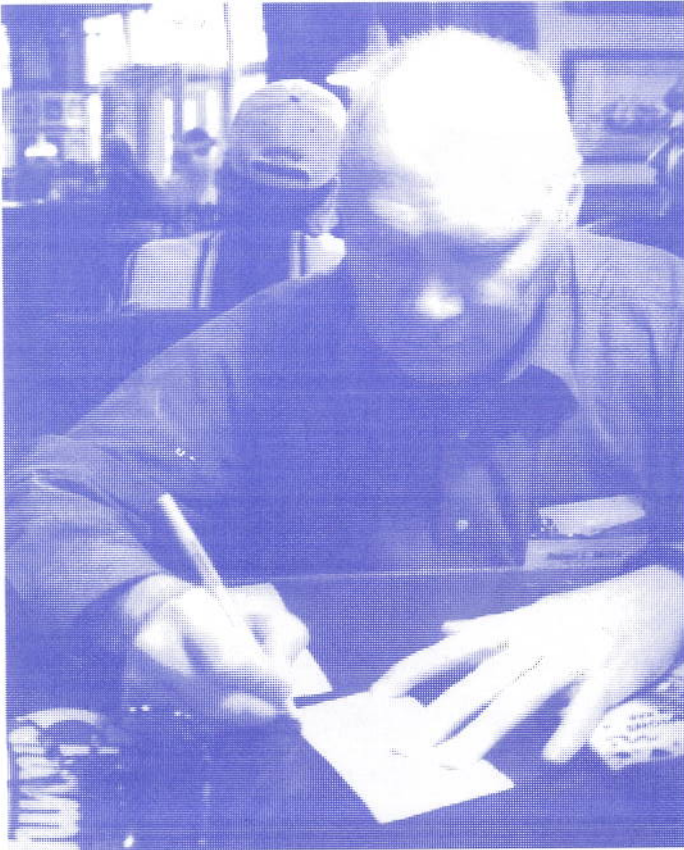


photo by Dyro

After the last beers, an hour passed as Morris talked about yak milk and laboratory analyzers. Finally, he picked up the tab confirming what many had long suspected that he did not have the slowest arm in the world

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Web Trappings

B.J. Morgan, Webmaster, jmorgan@ibm.net

As many of you are aware, the ACCE web server was down the last five days of June. This was due to a lightning strike on campus, which resulted in major damage to the power distribution system serving the computer center.

On a happier note, we have successfully moved the ACCE web site to another host with our own domain name. The URL of the new site is **www.acenet.org** or **accenet.org**, the www is optional. We are anticipating implementing several enhancements during the next year which were not possible with the old server. If you have any comments or suggestions, please contact me at jmorgan@ibm.net.

ACCE member Dr. Joe McClain reports that a Clinical Engineering Web Page has been established for Walter Reed Army Medical Center. The address of the new site is as follows:

<http://www.wramc.amedd.army.mil/departments/logistics/biomedical/ced/>
Joe also recommends visiting www.NCHES.org.



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Calendar of Events

- Annual Meeting, American Society of Physicists in Medicine, Aug. 9-13, 1998, San Antonio, TX. Phone 301-209-3350.
- 2nd Annual Orthopaedic Tissue Engineering, Aug. 10-12, 1998, Boston, MA. <http://www.biotech.nmhcc.org>; 888-670-8700 phone.
- 4th ACCE Teleconference, *ISO 9000* presented by David Simmons, August 20, 1998. Contact James O. Wear, 501-370-6618.
- Beacon Biosensor Symposium, October 2, 1998, Trinity College, Hartford, CT. Laurie MacFarlane: laurie.macfarlane@trincoll.edu; 860-297-5364.
- Biomedical Engineering Society Annual Meeting, Oct. 10-13, 1998, Cleveland, OH. Info: 216-444-5696 or 800-762-8173; 216-445-9406 fax.
- 20th Annual International Conference of IEEE Engineering in Medicine and Biology Society, October 29-November 1, 1998, Hong Kong, <http://www.ee.cuhk.edu.hk/embs98.html>.
- Advanced Clinical Engineering Workshop, Nov. 4-10, 1998, Mexico City. Joe Dyro 515-751-7244; jfdyro@aol.com.
- XXI National Biomedical Engineering Conference, Nov. 11-14, Mazatlán, Mexico. Info: Roberto Ayala at cmt@DNS.dsinet.com.
- IV International Conference on Clinical Engineering, Nov. 11-12, 1998 Mazatlán, Mexico. Adriana Velázquez at adrianavb@compuserve.com
- 18th Annual Northeastern Biomedical Symposium, Nov. 9-11, 1998 Albany, NY. Info: Ronald Hulin 518-525-1799; ibs98@aol.com.
- WSC '98, 1998 Winter Simulation Conference, Dec. 13-16, 1998, Washington, DC. <http://www.wintersim.org>.
- XXVth General Assembly of the International Union of Radio Science, Aug. 13-21, 1999, Toronto, Canada, 613-993-7271; ursi99@nrc.ca.
- BUDAMED '99, September 13-15, 1999, Budapest, Hungary. <http://www.fsz.bme.hu>; arato@fsz.bme.hu; (+361)463 2699 phone; 2204 fax.



Mr. Antonio Hernandez
PAHO
525 Twenty-Third Street, N.W.
Washington, DC 20037-2895
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November 4-10, 1998
Mexico City, Mexico

contact: JoeDyro, jfdyro@aol.com 516-751-7244; 7802 fax

ACCE Board Highlights

June 1, 1998

Jennifer C. Ott, Ottj@slucare1.sluh.edu

President Frank Painter reported that the First ACCE Symposium met expectations and was well received by the participants. One of the goals of the Symposium, the substantial interchange of information, was achieved. ACCE will continue to work with other organizations to ensure that future Symposia does not conflict with competing programs. HealthTech '98 in Nashville saw 24 ACCE members in attendance, many of whom made presentations at the event. The Teleconference program continues to be successful. Painter lead a discussion on ways by which participation in this valuable educational service can be increased. **Secretary** Jennifer Ott's report indicated that she was 8 months and 28 days pregnant thus unable to read the report in person. Plaques have been prepared for the three named ACCE Fellows this year. ACCE membership pins are on order. The Membership Directory will be mailed this summer. **Treasurer** Bryanne Patail reported a sound financial balance sheet with adequate reserves. Patail has improved and streamlined the budget process to allow year-to-year comparisons. After a brief discussion on the matter the Board approved a motion for Bryanne to head a three-person committee to advise on appropriate ways to invest excess funds. Payment of membership dues will be possible by way of credit card in the future. The Board unanimously approved the recommendation, presented by Kelly Galanopoulos, Chair of the **Membership Committee**, of three new members. **Education Committee** Chair Jim Wear presented the topics for the 1998 teleconferences (see pages 4-5, this issue of *ACCE News*). Advertising plans were presented. **Advocacy Committee** Chairman Tom O'Dea repeated his concerns over the ebb in advocacy-based CE publications. A \$200 cash award for recipients of the Advocacy Awards was approved. O'Dea requested suggestions for new committee members. **International Committee** Chairman Al Levenson announced the postponement of the ACEW in China. **Nominating Committee** Chairman Tom Bauld listed candidates for election this year. Painter updated the Board on **Advanced Clinical Engineering Workshop** plans for November 1998 in Mexico City. The curriculum is set as are format, faculty and size of student body. Practicums will be held in Mexico area hospitals. Local speakers have agreed to participate. Adriana Velázquez has arranged for local vendor support. Antonio Hernandez indicated PAHO support. Tom Judd indicated that ACCE member Andrei Issakov on behalf of the World Health Organization requested ACEWs for Moscow, Moldova, Sri Lanka, Africa and Kurdistan. Painter lead a discussion on Joe Bronzino's request to host an ACEW at Trinity College in Hartford in the Spring of 99. Those interested in participating as faculty should contact Frank Painter. **Past President** Tom Bauld announced that the ACCE position paper concerning the FDA ANPR will be sent to FDA in June. **Web Meister** Bruce Morgan announced moving the server to a more reliable commercial site. The new ACCE domain is accenet.org. The Board will meet next on August 26, 1998.

